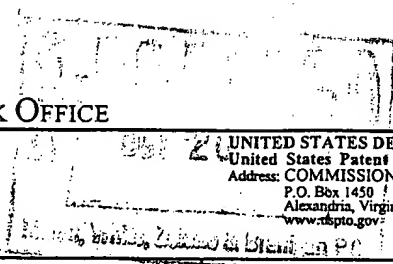




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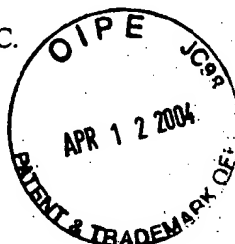


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/149,917	10/17/2002	Naoto Miwa	SCH 1899	4697

23599 7590 10/16/2003

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ARLINGTON, VA 22201



EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/16/2003

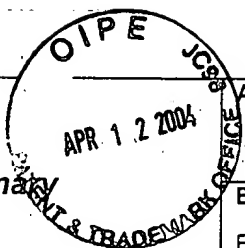
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Please find below and/or attached an Office communication concerning this application or proceeding.

CASE _____
ACTION Response Due
DUE DATE 1/16/04

CASE _____
ACTION _____
DUE DATE 1-16-2004
BCJ

OKT-D
10/27/03
[Signature]



Office Action Summary

Application No.

10/149,917

Examiner

Evelyn Huang

Applicant(s)

MIWA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 and 6 is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 8 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 1-8 are pending.

Priority

2. This application is a 371 of PCT/EP99/09959. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first compound on page 87 is the same as the last compound on page 88.

Duplicate Claims

4. Claim 2 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno (4839265). The instant claims are drawn to a composition comprising the specific dye compound. Any composition comprising the instant compound would meet the claims as recited since the intended use is given no weight in the composition claims.

Ohno generically discloses a dye compound which absorbs light in the infrared region, and the composition thereof (column 3, Formula (I)), which encompass the instant. Specific example compounds are described (columns 5-6, compound I-8; columns 7-8, compound I-13; columns 11-12, compounds I-29, I-30).

Ohno's example compounds I-8 and I-29 are the same as the compounds of instant claims 8 and 2 respectively except that Ohno's compounds are in the form of K salt, whereas the instant compounds are in the form of Na salt.

Ohno, however, teaches that K and Na salts are optional choices (column 3, lines 22-23). An example of Na salt is found on columns 9-10, compound I-19.

At the time of the invention, one of ordinary skill in the art would be motivated to prepare the exemplified, alternative Na salt and preparing a composition thereof to arrive at the instant invention with the reasonable expectation of obtaining an additional composition comprising the Na salt compound with light absorption at the IR region.

The compound of instant claim 4 additionally has $-(CH_2)_4SO_3$ whereas Ohno's compound I-30 has $-(CH_2)_3SO_3$ on the ring nitrogen. The instant is therefore the next adjacent homolog of Ohno's compound. Furthermore, Ohno teaches that $-(CH_2)_3SO_3$ and $-(CH_2)_4SO_3$ are optional choices (column 3, lines 34-36). Example of $-(CH_2)_4SO_3$ is found on columns 11-12, compound I-29.

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The compound of instant claim 5 additionally has $-(\text{CH}_2)_2\text{SO}_3$ whereas Ohno's compound I-13 has $-(\text{CH}_2)_4\text{SO}_3$ on the ring nitrogen. Ohno teaches that $-(\text{CH}_2)_2\text{SO}_3$ and $-(\text{CH}_2)_4\text{SO}_3$ are optional choices (column 3, lines 34-36). Examples of $-(\text{CH}_2)_2\text{SO}_3$ are found on columns 7-8, compound I-18 and columns 9-10, compound I-25.

At the time of the invention, one of ordinary skill in the art would be motivated to prepare the exemplified homologous compound and preparing a composition thereof to arrive at the instant invention with the reasonable expectation of obtaining an additional composition comprising the compound with light absorption at the IR region.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 32 of copending Application No. 09/787394, assuming that the copending claim is directed to a near infrared fluorescent contrast agent comprising the sodium salt of claim 30 (not claim 31 as recited). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-34 of copending Application No. 09/787394 (US equivalent to WO 00/16810, PTO-1449) and the corresponding claims in 10/324010 (divisional of 09/787394). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The composition comprising the compound of instant claim 8 is encompassed by the composition of copending claim 31 of 09/787394. The compound of copending claim 30 of 09/787394 is identical to the 4th compound of instant claim 1 and the compound of instant claim 5. At the time of the invention, one of ordinary skill in the art would be motivated to prepare the composition comprising the copending compound of 09/787394 with near infrared absorption to arrive at the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

8. Claims 2, 6 are allowed.

Fabricius (5440042) discloses an indolenine thioheterocyclic near infrared dye (columns 13-14, Table 1, compound D-5) which has a pyrimidinyl-thio whereas the instant has a substituted pyridone or pyrazolyl on the cyclopentenyl ring. Motivation to modify the prior art compound to arrive at the instant is lacking.

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Specification

9. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang

Primary Examiner

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